



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2013-N-1317]**

**Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the notice that appeared in the Federal Register of November 8, 2013 (78 FR 67169). In the notice, we requested comments on our tentative determination that partially hydrogenated oils (PHOs) are not generally recognized as safe (GRAS) for any use in food based on current scientific evidence, and therefore are subject to regulation as food additives. We are taking this action in response to multiple requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the notice. Submit either electronic or written comments by March 8, 2014.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2013-N-1317 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

## Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-1317 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Mical Honigfort, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1278, FAX: 301-436-2972, email: [mical.honigfort@fda.hhs.gov](mailto:mical.honigfort@fda.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### I. Background

In the Federal Register of November 8, 2013 (78 FR 67169), FDA published a notice announcing our tentative determination that PHOs, which are the primary dietary source of industrially-produced trans fatty acids, or trans fat, are not GRAS for any use in food based on current scientific evidence establishing the health risks associated with the consumption of trans

fat with a 60-day comment period ending on January 7, 2014. The notice also invited comments and additional scientific data and information related to this tentative determination and, in particular, requested comment on a number of specific questions (78 FR 67169 at 67174).

We have received multiple requests for a 60-day extension of the comment period for the notice. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to collect data and information and develop a comprehensive and thoughtful response to the notice.

FDA has considered the requests and is extending the comment period for the notice for 60 days, until March 8, 2014. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying our final determination on this important issue.

## II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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